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10/011,011	11/19/2001	Francisco Sureda	14XZ00088	7584

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EXAMINER	
ALHIJA, SAIF A	

ART UNIT	PAPER NUMBER
2128	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/011,011	SUREDA ET AL.	
	Examiner	Art Unit	
	Saif A. Alhija	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/09/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-58 have been presented for examination.

PRIORITY

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on **9 November 2001** is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner has considered the IDS as to the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-56, and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 contains no positive recited steps but rather an inference that a method has an intended use and therefore the claim does not produce a useful, concrete, and tangible result.

Claim 58 recites a computer program. It should be noted that code (i.e., a computer software program) does not do anything per se. Instead, it is the code stored on a computer that, *when executed*, instructs the computer to perform various functions. The following claim is a generic example of a proper computer program product claim;

A computer program product embodied on a computer-readable medium and comprising code that, when executed, causes a computer to perform the following:

Function A
Function B
Function C, etc...

Claims 2-56 are rejected by virtue of their dependency.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-57 are rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is an intended use rather than acts or steps to perform a method and is therefore indefinite.

Claim 57 contains the phrase "to a means a pick-up system." It is unclear what is meant by this phrase and therefore renders the claim vague and indefinite.

Claims 2-56 are rejected by virtue of their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-58 are rejected** under 35 U.S.C. 102(b) as being clearly anticipated by **Haridas et al, Medical Device and Diagnostic Industry Magazine "Predictive Analysis at the Forefront of Medical Product Development"**, hereafter referred to as **Haridas.**

Regarding Claim 1:

Haridas discloses Method for simulating the diameter enlargement of a lesion of a blood vessel by means of an endovascular prosthesis, wherein a three-dimensional simulated image is visualized,

showing the result of interaction between the lesion and the endovascular prosthesis after deployment of the latter, obtained by superposition of two three-dimensional images. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 2:

Haridas discloses Method according to claim 1, wherein the two three-dimensional images comprise a first three-dimensional simulated image showing the endovascular prosthesis deployed, taking into account the resistance of the lesion, and a second three-dimensional simulated image showing the enlarged lesion following the deployment of the endovascular prosthesis. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 3:

Haridas discloses Method according to claim 2, wherein the first three-dimensional simulated image showing the endovascular prosthesis deployed is obtained from a model of the implant. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 4:

Haridas discloses Method according to claim 3, wherein the model of the implant is obtained from the mechanical characteristics of the prosthesis or from characteristics of the prosthesis and a three-dimensional image of the contracted prosthesis. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 5:

Haridas discloses Method according to one of claim 2, wherein the second three-dimensional simulated image showing the enlarged lesion is obtained from a model of the lesion. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 6:

Haridas discloses Method according to one of claim 3, wherein the second three-dimensional simulated image showing the enlarged lesion is obtained from a model of the lesion. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 7:

Haridas discloses Method according to one of claim 4, wherein the second three-dimensional simulated image showing the enlarged lesion is obtained from a model of the lesion. **(Page 4, "What If" Material Sensitivity Studies. Page 6, Figure 8)**

Regarding Claim 8:

Haridas discloses Method according to claim 2, wherein the model of the lesion is obtained from the composition and biomechanical properties of the blood vessels and surrounding atheromatous plaques and from a three-dimensional image of the lesion. **(Page 6, Paragraph 2)**

Regarding Claim 9:

Haridas discloses Method according to claim 3, wherein the model of the lesion is obtained from the composition and biomechanical properties of the blood vessels and surrounding atheromatous plaques and from a three-dimensional image of the lesion. **(Page 6, Paragraph 2)**

Regarding Claim 10:

Haridas discloses Method according to claim 4, wherein the model of the lesion is obtained from the composition and biomechanical properties of the blood vessels and surrounding atheromatous plaques and from a three-dimensional image of the lesion. **(Page 6, Paragraph 2)**

Regarding Claim 11:

Haridas discloses Method according to claim 5, wherein the model of the lesion is obtained from the composition and biomechanical properties of the blood vessels and surrounding atheromatous plaques and from a three-dimensional image of the lesion. **(Page 6, Paragraph 2)**

Regarding Claim 12:

Haridas discloses Method according to claim 3, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 13:

Haridas discloses Method according to claim 4, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 14:

Haridas discloses Method according to claim 5, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 15:

Haridas discloses Method according to claim 6, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 16:

Haridas discloses Method according to claim 7, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 17:

Haridas discloses Method according to claim 8, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 18:

Haridas discloses Method according to claim 9, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 19:

Haridas discloses Method according to claim 10, wherein, for particular parameters concerning the deployment technique, the lesion and the vascular prosthesis, the biomechanical properties of the lesion are taken into account to execute the model of the prosthesis in order to obtain a three-dimensional image of the prosthesis deployed, and then to execute the model of the lesion in order to obtain a three-dimensional image of the enlarged lesion. **(Page 6, Paragraphs 1-2)**

Regarding Claim 20:

Haridas discloses Method according to claim 3, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 21:

Haridas discloses Method according to claim 4, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 22:

Haridas discloses Method according to claim 5, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 23:

Haridas discloses Method according to claim 6, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 24:

Haridas discloses Method according to claim 7, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 25:

Haridas discloses Method according to claim 8, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page**

5, Paragraph 1. Figure 7)

Regarding Claim 26:

Haridas discloses Method according to claim 9, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 27:

Haridas discloses Method according to claim 10, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 28:

Haridas discloses Method according to claim 11, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 29:

Haridas discloses Method according to claim 12, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 30:

Haridas discloses Method according to claim 13, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 31:

Haridas discloses Method according to claim 14, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 32:

Haridas discloses Method according to claim 15, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 33:

Haridas discloses Method according to claim 16, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 34:

Haridas discloses Method according to claim 17, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 35:

Haridas discloses Method according to claim 18, wherein the model of the prosthesis is established as a function of the radial pressure and resistance forces on the mesh of the prosthesis. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 36:

Haridas discloses Method according to claim 5, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 37:

Haridas discloses Method according to claim 6, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 38:

Haridas discloses Method according to claim 7, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 39:

Haridas discloses Method according to claim 8, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 40:

Haridas discloses Method according to claim 9, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 41:

Haridas discloses Method according to claim 10, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 42:

Haridas discloses Method according to claim 11, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 43:

Haridas discloses Method according to claim 12, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 44:

Haridas discloses Method according to claim 13, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 45:

Haridas discloses Method according to claim 14, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 46:

Haridas discloses Method according to claim 15, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 47:

Haridas discloses Method according to claim 16, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 48:

Haridas discloses Method according to claim 17, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 49:

Haridas discloses Method according to claim 18, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 50:

Haridas discloses Method according to claim 19, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 51:

Haridas discloses Method according to claim 20, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 52:

Haridas discloses Method according to claim 21, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 53:

Haridas discloses Method according to claim 22, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 54:

Haridas discloses Method according to claim 23, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 55:

Haridas discloses Method according to claim 24, wherein the model of the lesion is established by means of the finite-element method. **(Page 5, Paragraph 1. Figure 7)**

Regarding Claim 56:

Haridas discloses Method according to claim 1, wherein on an effective deployment of the prosthesis in the lesion, the instantaneous state of the endovascular prosthesis and shape of the lesion are taken into account in order to simulate and visualize in three dimensions a future state of the endovascular prosthesis and of the lesion as a function of possible actions indicated by an operator. **(Page 4, "What If" Material Sensitivity Studies. Page 5, Paragraph 1. Page 6, Paragraphs 1-2. Figure 7-8)**

Regarding Claim 57:

Haridas discloses System to simulate the diameter enlargement of a lesion of a blood vessel comprising:

means for providing an endovascular prosthesis; means for providing a computer equipped with data storage; means for processing and display; **(Page 4, "What If" Material Sensitivity Studies. Page 5, Paragraph 1. Page 6, Paragraphs 1-2. Figure 7-8)**

means for visualizing a three-dimensional simulated image showing the result of interaction between the lesion and the endovascular prosthesis after deployment of the prosthesis, the three-dimensional simulated image being obtained by superposition of two three-dimensional images; **(Page 4, "What If" Material Sensitivity Studies. Page 5, Paragraph 1. Page 6, Paragraphs 1-2. Figure 7-8)**

and the means for providing a computer being optionally connected to a means a pick-up system. **(Page 4, "What If" Material Sensitivity Studies. Page 5, Paragraph 1. Page 6, Paragraphs 1-2. Figure 7-8)**

Regarding Claim 58:

Haridas discloses A computer data storage means comprising a computer program, which enables a computer to execute:

the procedure of synthesis of the model of an endovascular prosthesis and of the model of a lesion of a blood vessel in order to simulate the interaction between the lesion and the endovascular prosthesis after deployment of the latter, and the procedure of display on a screen of a three-dimensional simulated image showing the result of the interaction. **(Page 4, "What If" Material Sensitivity Studies. Page 5, Paragraph 1. Page 6, Paragraphs 1-2. Figure 7-8)**

Conclusion

7. All Claims are rejected.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saif A. Alhija whose telephone number is (571) 272-8635. The examiner can normally be reached on M-F, 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah can be reached on (571) 272-2279. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAA

March 2, 2006

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